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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte YONGWEI CAO and WILLIAM E. TIMBERLAKE

Appeal 2008-0751
Application 09/819,091
Technology Center 1600

Decided: March 14, 2008

Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1 and 8-11, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to a substantially purified nucleic acid molecule. Claim 8 is illustrative:

8. A substantially purified nucleic acid molecule, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 90% identity to the nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

The Examiner relies on the following prior art references to show unpatentability:

Andrew B. Sparks et al., "Distinct ligand preferences of Src homology 3 domains from Src, Yes, Abl, Cortactin, p53bp2, PLCγ, Crk, and Grb2," 93 *Proc. Natl. Acad. Sci. USA,* 1540-1544 (1996.)

James C. Whisstock et al., "Prediction of protein function from protein sequence and structure," 36(3) *Quarterly Reviews of Biophysics*, 307-340 (2003).

The rejections as presented by the Examiner are as follows:

1. Claims 1 and 8-11 stand rejected under 35 U.S.C. § 101 and the enablement provision of 35 U.S.C. § 112, first paragraph as lacking a patentable utility.

2. Claims 8-11 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

We affirm the utility rejection and reverse the written description rejection.

DISCUSSION

The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Therefore, we limit our discussion to representative claim 8. Claim 8 is drawn to a substantially purified nucleic acid molecule, wherein said nucleic acid molecule comprises a nucleic acid

sequence having between 100% and 90% identity to the nucleic acid sequence of SEQ ID NO: 1 or complement[1] thereof.

Utility:

The Examiner finds that the claimed invention is "not supported by either a specific and substantial asserted utility or a well-established utility" (Ans. 4). In this regard the Examiner finds:

1. the nucleic acid of SEQ ID NO: 1 was isolated from a library prepared from *Arabidopsis thaliana* tissue (Ans. 5).

2. Table 1 of Appellants' Specification discloses that "the nucleic acid of SEQ ID NO: 1 shares 84% identity with a nucleic acid encoding an 'unknown protein with Src homology 3 (SH3) domain profile'" (*id.*).

3. Appellants' Specification "does not set clearly forth a particular biological activity of a putative protein encoded by SEQ ID NO: 1" (*id.*).

4. "There is no showing that the protein encoded by SEQ ID NO: 1 does in fact contain a SH3 domain profile" (*id.*).

5. "Even if it is determined that the protein encoded by SEQ ID NO: 1 has a SH3 domain profile, the specification has not established that the presence of the SH3 domain profile imparts a specific biological activity to the encoded protein" (*id.*).

6. A "finding that a protein has a SH3 domain or shares identity with a protein having an SH3 domain does not apprise one of skill in the art of a specific biological activity associated with said protein" (*id.*).

[1] "A nucleic acid molecule is said to be the 'complement' of another nucleic acid molecule if they exhibit complete complementarity. As used herein, molecules are said to exhibit 'complete complementarity' when every nucleotide of one of the molecules is complementary to a nucleotide of the other" (Specification 18: 13-17).

7. "Proteins having SH3 domains are significantly diverse with respect to the ligands that they bind and with respect to their overall functional activities" (*id.*).

8. "Sequence and structural homology between different nucleotide and amino acid sequences are not necessarily correlated with functional activity since proteins having SH3 domains may have very distinct biological activities" (Ans. 6).

9. Whisstock "teaches that '. . .prediction of protein function from sequence and structure is a difficult problem, because homologous proteins often have different functions. . . . [Prediction] methods provide reasonable guesses at function, but are far from foolproof'" (*id.* (quoting Whisstock 307: Abstract)).

10. Appellants'

> specification (page 39) states that the claimed nucleic acids can be used to obtain other nucleic acids from the same species or to isolate homologous nucleic acids from other species. However, . . . [s]uch uses allow only for the identification and analysis of other nucleic acids which in turn will also lack a specific and substantial utility in the absence of any specific function or activity attributed to the protein encoded by SEQ ID NO[:] 1.

(*Id.*)

11. Appellants'

> specification (page 39-40) further contemplates that the nucleic acid of SEQ ID NO: 1 can be used for mapping studies, linkage analysis, constructing transgenic plants, screening for traits or screening for polymorphisms. However, these uses are applicable to a broad class of molecules since all plant nucleic acids could be used for these purposes. Thereby, these uses are general and do not constitute a specific utility.

(Ans. 6-7). Further, "Appellants have not established that the claimed nucleic acid or protein [encoded by this nucleic acid] could be used to identify a particular trait or to detect a particular polymorphism or promoter of known function" (Ans. 9).

12. Appellants' Specification asserts that the nucleic acid of SEQ ID NO: 1 can be used "for antisense methods to 'prevent or reduce gene function'"; "to synthesize protein, which could then be used in conducting further research to characterize the protein"; and to produce protein that "could be used to generate antibodies which could be used for detection purposes" (Ans. 7-8). However, each of these stated utilities constitutes further research in an effort to identify the utility of the claimed nucleic acid.

Based on these findings, the Examiner concludes that "the claimed invention is not supported by either a specific [or] substantial asserted utility or a well-established utility" (Ans. 9).

In response, Appellants assert that Table 1, page 92 of their Specification establishes "that SEQ ID NO: 1 shares a significant identity to a protein with Src homology 3 (SH3) domain profile" (App. Br. 4). Directing attention to Sparks, Appellants assert that "one of ordinary skill in the art would readily recognize the importance of proteins having SH3 domains, for example in signal transduction" (*id.*). We are not persuaded.

As the Examiner points out, Sparks teaches that

A. "SH3 domains vary with respect to the ligands that they bind and that 'the ligand preferences of most SH3 domains and the role of these preferences in regulating SH3-mediated protein-protein interactions remain poorly defined'" (Ans. 16).

B. SH3 domains are able to discern subtle differences in the primary structure of potential ligands, such that '(e)ach SH3 domain selects a set of peptide ligands sharing a distinct consensus motif; these motifs reflect the unique ligand preferences of each SH3 domain'" (*id.*).

C. "[P]roteins having SH3 domains may play a role in [a] wide variety of biological activities" (*id.*).

As the Examiner explains, Appellants' Specification does not identify: "a particular SH3 domain present in the protein encoded by SEQ ID NO: 1"; "a ligand that binds to a SH3 domain of a protein encoded by SEQ ID NO: 1"; or "a specific biological activity associated with the binding of a ligand to a SH3 domain of a protein encoded by SEQ ID NO: 1" (Ans. 17). Accordingly, we are not persuaded by Appellants' assertion that "[s]ignal transduction is a specific biological activity that satisfies the utility requirements of 35 U.S.C. § 101" for their claimed nucleic acid (App. Br. 6). Even if a protein encoded by SEQ ID NO: 1 is actually involved in signal transduction, a person of ordinary skill in the art is left to perform additional research in order to identify which ligand this protein interacts with and which activity, of the many different activities exhibited by proteins with SH3 domains, this protein will have.

For the foregoing reasons, we disagree with Appellants' assertion that "the utility of nucleic acid molecules having the sequence of SEQ ID NO: 1 is *substantial*" (App. Br. 7).

Appellants assert that their Specification "discloses that nucleic acid molecules such as SEQ ID NO: 1 *may* contain promoter regions or partial promoter regions" (App. Br. 8 (emphasis added)). In support of this assertion Appellants refer to pages 2 to 4 of their September 11, 2006 response (*id.*). According to Appellants nucleotides 957 to 963 of SEQ ID NO: 1 contain the "nucleotides TATAAA [which] is the consensus sequence for a TATA box" and that nucleotides 897 to 901 contain "another conserved sequence known as the CAAT box" (September 11, 2006 Response 2). From this Appellants conclude that their "claimed nucleotide sequence can perform as a promoter" (*id.*). We are not persuaded.

Attorney argument cannot take the place of evidence lacking in the record. *Meitzner v. Mindick*, 549 F.2d 775, 782 (CCPA 1977). Further, as the Examiner explains, Appellants'

> specification (page 23) states that promoters can include between about 300 bp upstream and about 10kb upstream of the trinucleotide ATG sequence at the start site of a protein coding region. . . . SEQ ID NO: 1 consists of 1093 nucleotides. The specification does not identify the first ATG start site of a protein coding region. However, the first potential ATG start site occurs at nucleotides 22-24 of SEQ ID NO: 1. As such, the nucleic acid of SEQ ID NO: 1 does not appear to include 300 to 10kb upstream sequences that may contain a potential promoter region.

(Ans. 18.) Simply stated, there is no evidence on this record to support Appellants' assertion that the nucleotide sequence set forth in claim 8 will

function as a promoter. Accordingly, we are not persuaded by Appellants' argument to the contrary.

In sum, we agree with the Examiner that the Specification does not disclose a utility for the claimed nucleic acid that satisfies 35 U.S.C. § 101. Section 101 requires a utility that is both substantial and specific. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). A substantial utility must "show that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." *Id.* A specific utility is "a use which is not so vague as to be meaningless." *Id.* In other words, "in addition to providing a 'substantial' utility, an asserted use must also show that th[e] claimed invention can be used to provide a well-defined and particular benefit to the public." *Id.*

For the foregoing reasons, we affirm the rejection of claim 8 under 35 U.S.C. § 101 as lacking a patentable utility. Claims 1 and 9-11 fall together with claim 8.

Enablement:

As a corollary to the rejection under 35 U.S.C. § 101, the Examiner also rejected claims 1 and 8-11 under the enablement provision of 35 U.S.C. § 112, first paragraph, finding that "since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility . . . one skilled in the art would not know how to use the claimed invention" (Answer 9). We agree.

We note, however, Appellants' assertion that "the abstract of Whisstock *et al.* cited by the Examiner clearly states that methods of predicting protein function from sequence 'provide reasonable guesses at function" (App. Br. 9). Appellants' citation of Whisstock is not complete. The complete sentence of Whisstock relied upon by Appellants states "that 'such methods provide reasonable guesses at function, *but are far from foolproof*'" (Whisstock 307: Abstract). According to Whisstock, "[i]n most cases, predictions suggest, but do not determine, the general class of function. Their most useful effect is to guide investigations in the laboratory to confirm, or refute, the prediction, and, even if correct, to define the function in greater detail" (Whisstock 335: 24-27). Thus, according to Whisstock, predicting protein function from amino acid sequence homology is a tool, or starting point, upon which to guide further research.

Weighing on this idea of a "reasonable guess" at the true function of any given protein is that "[e]ven if it is possible to ascribe a particular function to a gene product, the protein may have multiple functions" (Whisstock 307: Abstract). While Appellants assert that a putative protein encoded by their claimed nucleic acid sequence has 84 percent identity with a protein with a SH3 domain profile (App. Br. 9), the evidence on this record establishes that proteins with SH3 domain profiles exhibit a variety of different activities (Sparks 1540; Ans. 16-17).

Accordingly, we disagree with Appellants' assertion "that the claimed invention has a credible, substantial, specific or well-established utility" (App. Br. 9). Accordingly, we affirm the rejection of claim 8 under the enablement provision of 35 U.S.C. § 112, first paragraph. Claims 1 and 9-11 fall together with claim 8.

Written Description:

Claims 8-11 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph. We will reverse this rejection.

The Federal Circuit has held that "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997).

Our appellate reviewing court has also held that the complete structure of a claimed DNA is not necessarily required. The court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1324 (Fed. Cir. 2002) (emphasis omitted, alterations in original).

With respect to the claimed sequences that have 90% to 100% identity with SEQ ID NO:1 or complement thereof, the *Lilly* court held that a genus could be described via "recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Lilly*, 119 F.3d at 1569. The *Enzo* court held that such a description could take the form of "complete or partial structure, other physical and/or

chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Id.* 296 F.3d at 1324. In this case, the complete structure of SEQ ID NO:1 has been described, and the nucleic acids of the claimed genus share 90 or more percent identity with the structure of SEQ ID NO:1 or complement thereof. Thus, the structural features that are common to the genus make up 90% of the structure of the claimed polypeptides.

Importantly, with respect to this rejection, the claimed nucleic acids are defined solely by structural limitations. They are not limited only to a subset (e.g., those encoding functional proteins) of the structurally similar nucleic acids. Given enough time or a powerful enough computer, a skilled artisan could generate a list of every nucleic acid that is 90% identical to SEQ ID NO: 1 or its complement. In view of the lack of functional limitations, the Examiner has not adequately explained why a description of SEQ ID NO: 1 does not adequately describe sequences that are 90-100% identical to SEQ ID NO: 1.

Accordingly, we reverse the rejection of claims 8-11 under the written description provision of 35 U.S.C. § 112, first paragraph.

CONCLUSION

In summary, we affirm the rejection of claims 1 and 8-11 under 35 U.S.C. § 101 and the enablement provision of 35 U.S.C. § 112, first paragraph as lacking a patentable utility. We reverse the rejection of claims 8-11 under the written description provision of 35 U.S.C. § 112, first paragraph.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

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